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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/764,799	01/26/2004	Jack W. Szostak	COTH-P08-701	1174

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101 FEDERAL STREET  
BOSTON, MA 02110

EXAMINER
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FORMAN, BETTY J

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 09/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/764,799

Applicant(s)

SZOSTAK ET AL.

Examiner

BJ Forman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 24-53 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 24-53 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_.

## **DETAILED ACTION**

### ***Interference***

1. Claims 24-53 of this application have been copied from U. S. Patent No. 6,361,943. However, an interference cannot be established at this time because the instant claims are not in condition for allowance.

Claims 1 and 24-53 are under prosecution and rejected as discussed below.

### ***Priority***

2. Applicant's claim for priority under 35 U.S.C. 119(e) and 120 is acknowledged. However, the parent applications upon which priority is claimed do not provide adequate support under 35 U.S.C. 112 for claims 24-53 of this application.

Claims 24-53 were added in a preliminary amendment dated 27 September 2002. Independent Claims 24 and 40 are drawn to linking chemical structures not described in the priority documents or instant specification. In papers filed 30 April 2003, Applicant points to provisional application 60/035,963, page 2, lines 12-21, page 5, lines 11-12 and page 16, lines 1-20 for support of the new claims. The cited passages (and the entire disclosure) have been thoroughly reviewed, but a supportive teaching is not found.

Claim 24 is drawn to linking structures "selected from the group consisting of puromycin, 3'-N-aminoacylpuromycin aminonucleoside, and 3'-N-aminoacyladenosine aminonucleoside".

Claim 40 is drawn to linking structures "selected from the group consisting of puromycin, an analog of puromycin, and 3'-N-aminoacyladenosine aminonucleoside".

The '963 priority document (page 16, lines 1-20) provides examples of linking structures i.e. "puromycin (or any other appropriate peptide acceptor)", "puromycin-like compounds",

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“puromycin-like 3' ends”, and “other peptide acceptors which may be used include, without limitation, any compound which possesses an amino acid linked to an adenine or an adenine-like compound, such as the amino acid nucleotides, phenylalanyl-adenosine (A-Phe), tyrosyl adenosine (A-Tyr), and alanyl adenosine (A-Ala), as well as amide-linked structures, such as phenylalanyl 3' deoxy 3, amino adenosine, alanyl 3' deoxy 3, amino adenosine, and tyrosyl 3' deoxy 3' amino adenosine; in any of these compounds, any of the naturally-occurring L-amino acids or their analogs may be utilized.”

The cited passage teaches the broad genus “puromycin-like” and “peptide acceptors”. The cited passage further teaches specific species.

The instant claims, while drawn to puromycin, are further drawn to specific species of chemical linkers not described in any of the priority documents. While the genus “puromycin-like” or “peptide acceptors” may encompass the newly claimed species, the specification provides no guidance for selecting the instantly claimed species.

Because the parent applications do not provide support under 35 U.S.C. 112, for the instant claims, the effective filing date for Claims 24-53 is the filing date of the instant application i.e. 26 January 2004.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States

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before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 24-53 are rejected under 35 U.S.C. 102(e) as being anticipated by Yanagawa et al (U.S. Patent No. 6,361,943, filed 2 June 1998).

As Applicant notes in papers filed 26 January 2004, the instant claims correspond exactly or substantially to Claims 1-6, 10-12, 15, 16 and 19-23 of Yanagawa. Because the effective filing date of the '943 patent is earlier than the effective filing date for instant claims 24-53, the '943 patent qualifies as prior art for the instant claims.

5. Claims 24-53 are rejected under 35 U.S.C. 102(b) as being anticipated by Yanagawa et al (WO 98/16636, published 23 April 1998).

The Yanagawa patent cited above, is the national stage for PCT WO 98/16636. Therefore, the PCT discloses the same invention as the '943 patent. Because the effective filing date for the instant claims is more than a year after the publication date for the PCT, the PCT qualifies as prior art under 35 U.S.C. 102(b).

6. Claim 1 rejected under 35 U.S.C. 102(e) as being anticipated by Szostak et al (U.S. Patent No. 6,261, 804, filed 9 February 1999).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the

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inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Regarding Claim 1, the instant claim only differs from Claim 1 of the patent in that the '804 claim defines the peptide acceptor as a molecule that can be added to the C-terminus of a growing protein chain by the catalytic activity of a ribosomal peptidyl transferase. However, the open claim language "comprising" and genus peptide acceptor of the instant claim encompasses the species of peptide acceptor as defined in the patent claim.

The courts have stated that a genus is obvious in view of the teaching of a species see *Slayter*, 276 F.2d 408, 411, 125 USPQ 345, 347 (CCPA 1960); and *In re Gosteli*, 872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989). Therefore the instantly claimed genus peptide acceptor encompasses the '804 species peptide acceptor.

### ***Double Patenting***

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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8. Claim 1 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4-23 and 30-38 of U.S. Patent No. 6,261,804. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claims are drawn to a method for producing a protein library comprising identical steps of production. The claims only differ in that Claim 1 of the patent (from which all over claims depend) defines the peptide acceptor as a molecule that can be added to the C-terminus of a growing protein chain by the catalytic activity of a ribosomal peptidyl transferase. However, the open claim language "comprising" and genus peptide acceptor of the instant claim encompasses the species of peptide acceptor as defined in the patent claim. Furthermore, the open claim language "comprising" of instant Claim 1 encompasses the additional method steps recited in Claims 4-23 and 30-38 of the patent.

### **Conclusion**

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

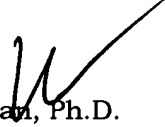
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.



BJ Forman, Ph.D.  
Primary Examiner  
Art Unit: 1634  
September 5, 2006